

Tramadol Listed as Schedule IV Controlled Substance in Kentucky

In response to significant concerns raised by healthcare professionals, the Kentucky Cabinet For Health and Family Services, Office of the Inspector General, Division of Audits and Investigations, Drug Enforcement and Professional Practices Branch submitted a request to the Kentucky Legislature to modify regulation 902 KAR 55:030 to add Tramadol to the list of Schedule IV controlled substance products in Kentucky.

The regulation change was adopted and will be effective on December 5, 2008. At that time any prescriber without a valid DEA license cannot write or issue a prescription for Tramadol. In addition, any remaining refills on a Tramadol prescription issued by a prescriber without a valid DEA license may not be dispensed. All provisions of 21 CFR Ch.II 1306.22 regarding refilling of controlled substance prescriptions should be followed. If you have a prescription from a DEA licensed prescriber with refills remaining and the prescription is not over 6 months from the date written it may be refilled.

Following are additional actions that should be taken by controlled substance dispensers, distributors and wholesalers, along with the appropriate statutory references.

Controlled substance dispensers must adhere to KRS 218A.200 (7)(b):

“A substance which is added to any schedule of controlled substances and which was not previously listed in any schedule shall be initially inventoried within thirty (30) days of the effective date of the statute or administrative regulation which adds the substance to the provisions of this chapter. Thereafter, the substance shall be included in the inventory required by paragraph (a) of this subsection. “

Controlled substance dispensers must report all dispensing of Tramadol to the Kentucky All Schedule Prescription Electronic Reporting (KASPER) system (KRS 218A.202 (3)).

Controlled substance distributors and wholesalers must adhere to KRS 218A.170:

“A duly licensed manufacturer, distributor, or wholesaler may sell or distribute controlled substances, other than samples”. As a result all Tramadol samples should be destroyed by a hazardous materials handler within 30 days or inventoried on a DEA 41 form and sent to a reverse distributor licensed by the DEA.

If you have any questions regarding this regulation change, please contact the Drug Enforcement and Professional Practices Branch at (502) 564-7985. Thank you for your prompt action and cooperation in this matter.